

MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient
-----------------------	--

INSTITUTE: National Institute of Child Health and Human Development

STUDY NUMBER: 04-CH-0056 PRINCIPAL INVESTIGATOR: Pamela Stratton, M.D.

STUDY TITLE: The Neural Immune Mechanisms and Genetic Influences on Chronic Pelvic Pain in Women with Endometriosis

Latest IRB Review: Initial Review 9/24/03

Latest Amendment Approved: Amend D 6/10/04

Screening Questionnaire

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Purpose of the Study

Chronic pelvic pain associated with endometriosis is poorly understood. This study is an effort to better understand pelvic pain and identify better medical approaches to treat it. Endometriosis is a disease in which uterine tissue grows outside the uterus. Currently we believe that the endometriosis causes chronic pelvic pain. Yet, some women with endometriosis do not have any pain and others have pain in areas that are not related to endometriosis disease location. The standard approaches to treating pain from endometriosis have been to medically alter hormone levels to prevent endometriosis tissue growth or surgically remove endometriosis. Yet pelvic pain is only temporarily treated by either approach. This evidence has told us that the current classification of pain based on disease and treatment based on surgery and medical alteration of hormones is not adequate.

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (4-97)

P.A.: 09-25-0099

File in Section 4: Protocol Consent (2)

MEDICAL RECORD**CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 04-CH-0056

CONTINUATION: page 2 of 3 pages

To determine if you might participate in the study, either because you have pelvic pain or want a tubal ligation we ask that you complete the enclosed questionnaire and return it to us. The questions relate to the location, type, timing and frequency of pain, as well as previous treatments and medical or social issues that may relate to your pain. We will use your answers to determine whether you may have endometriosis as a cause of your pain. One of the study investigators will call you to review your answers and then either schedule an appointment to discuss the study further or else discuss why you may be ineligible for our study. We ask your consent to use your responses as part of our research in pain as well as to understand your own medical condition. To do this, we will keep your answers in a locked file, and may publish them with others in a scientific journal. However, this will be done in a way so that your personal identity is not revealed.

Risk and Discomfort to You if You Take Part in this Study

Some people find that these types of questions make them feel uncomfortable. Filling in this questionnaire will take about 30 minutes of your time.

The Benefits to You of Taking Part in this Study

If you have pelvic pain, you may be eligible for a study that would diagnose and treat endometriosis, and would give you some relief from chronic pelvic pain. You may benefit from pain therapies that will be administered after surgery. If you don't have pelvic pain and want to be a healthy volunteer for this study, you would have a tubal ligation. Finally, other women may benefit from the knowledge obtained by this study including improvement in the diagnosis of endometriosis-related pain through questionnaires.

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

MEDICAL RECORD**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**

• Adult Patient or • Parent, for Minor Patient

STUDY NUMBER: 04-CH-0056

CONTINUATION: page 3 of 3 pages

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Pamela Stratton, M.D.; Building 10, Room 9D42, Telephone: 301-496-9079, Daniel Handel, MD, Telephone: 301-594-9767, James Segars, MD, Telephone: 301-295-6007, Jay Shah, MD, Telephone: 301-496-4412, Landis Vance, Associate Chaplin, Telephone: 301-496-3407 or, after hours, through the NIH page operator at 301-496-1211. You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:**A. Adult Patient's Consent**

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative Date**B. Parent's Permission for Minor Patient.**

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian Date**C. Child's Verbal Assent (If Applicable)**

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian Date

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM SEPTEMBER 24, 2003 THROUGH SEPTEMBER 24, 2004.**

Signature of Investigator_____
Date_____
Signature of Witness_____
Date**PATIENT IDENTIFICATION****CONSENT TO PARTICIPATE IN A CLINICAL
RESEARCH STUDY (Continuation Sheet)**

• Adult Patient or • Parent, for Minor Patient

NIH-2514-1 (5-98)

P.A.: 09-25-0099

File in Section 4: Protocol Consent